

4/3, K/22 (Item 1 from file: 156)  
DIALOG(R)File 156:Toxline(R)  
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02537123 Subfile: TOXBIB-92-113079

**Hair** growth effects of oral administration of finasteride, a steroid 5 alpha-reductase inhibitor, alone and in combination with topical minoxidil in the balding stumptail macaque.

**Diani AR;** Mulholland MJ; Shull KL; Kubicek MF; Johnson GA; Schostarez HJ; Brunden MN; Buhl AE

Upjohn Laboratories, Kalamazoo, Michigan 49001.

Source: J Clin Endocrinol Metab; VOL 74, ISS 2, 1992, P345-50 ISSN: 0021-972X Coden: HRB

Language: ENGLISH

Document Type: JOURNAL ARTICLE

**Hair** growth effects of oral administration of finasteride, a steroid 5 alpha-reductase inhibitor, alone and...

**Diani AR;** Mulholland MJ; Shull KL; Kubicek MF; Johnson GA; Schostarez HJ; Brunden MN; Buhl AE

... in combination with topical 2% minoxidil, for 20 weeks to determine the effects on scalp **hair** growth in balding adult male stumptail macaque monkeys. A 7-day dose-finding study showed...

... doses of the drug produced a similar diminution in serum dihydrotestosterone (DHT) in male stumptails. **Hair** growth was evaluated by shaving and weighing scalp **hair** at baseline and at 4-week intervals during treatment to obtain cumulative delta **hair** weight (sum of the 4-week changes in **hair** weight from baseline) for the 20-week study. The activity of the 5 alpha-reductase...

... DHT at 4-week intervals. The combination of finasteride and minoxidil generated significant augmentation of **hair** weight (additive effect) compared to either drug alone. Finasteride increased **hair** weight in four of five monkeys. When the data of the one nonresponsive monkey were excluded, finasteride elicited a significant elevation in **hair** weight compared to topical vehicle alone. Minoxidil also evoked a significant increase in **hair** weight compared to vehicle alone. Serum T was unchanged, whereas serum DHT was significantly depressed...

... T to DHT by this 5 alpha-reductase inhibitor reverses the balding process and enhances **hair** regrowth by topical minoxidil in the male balding stumptail macaque.

Descriptors/Keywords: Androstenes--Pharmacology--PD; \*Azasteroids--Pharmacology--PD; \***Hair**--Drug Effects--DE; \*Minoxidil--Pharmacology--PD; \*Testosterone 5-alpha-Reductase--Antagonists and Inhibitors--AI...; Administration and Dosage--AD; Azasteroids--Administration and Dosage--AD; Chromatography, High Pressure Liquid; Drug Interactions; **Hair**--Physiology--PH; Macaca; Minoxidil--Administration and Dosage--AD; Minoxidil--Urine--UR; Reference Values; Stanolone--Blood...

L5 ANSWER 7 OF 13 USPATFULL

SUMM . . . and 5%; vegetal proteolytic enzymes, specially papain between 0.1 and 2%, bromelain, between 0.1 and 0.5%; antialopecia products, such

as **progesterone** (between 1 and 3%) **minoxidil** (from 1-3%), tricopeptides (0.01-2%) and tricosacarides (0.1-2%), **hair** decolorants, specially mandarin essential oil (0.5-5%) and other **hair** growth retarding substances, such as alkyl-isoquinoleine bromide (0.2-3%).

SUMM . . . and 5%; vegetal proteolytic enzymes, specially papain between 0.1 and 2%, bromelain, between 0.1 and 0.5%; antialopecia products, such

as **progesterone** (between 1 and 3%), **minoxidil** (from 1-3%), tricopeptides (0.01-2%) and tricosacarides (0.1-2%), **hair** decolorants, specially mandarin essential oil (0.5-5%) and basic hydroquinone (1-3%); topical use antibiotics, specially basic erythromycin (1-3%), and clindamycin (0.5-1%);. . . and the association with other chemical antiandrogens (cyproterone acetate. Flutamide and Finasteride. Casodex, etc. between 0.01 and 2%) and other **hair** growth retarding substances, such as alkyl-soquinoleine bromide (0.2-5%).

PI US 6113926 20000905

L5 ANSWER 6 OF 13 USPATFULL

CLM What is claimed is:

8. The method of claim 7 which additionally comprises a second hair growth agent selected from the group consisting of zinc salts of carboxylic acids, saponins, other triterpenes such as oleanolic acid and ursolic acid, crataegolic acid, celastrol, asiatic acid, inhibitors of 5-.alpha.-reductase such as **progesterone**, 1,4-methyl-4-azasteroids, in particular 17-.beta.-N,N-diethylcarbamoyl-4-methyl-4-aza-5-.alpha.-androstan-3-one, androgen receptor antagonists such as cyproterone acetate, **Minoxidil.RTM.**, azelaic acid and its derivatives, cyclosporin, triiodothyronine, diazoxide, potassium channel openers such as cromakalin, phenytoin and mixtures thereof.

PI US 6124362 20000926

L12 ANSWER 23 OF 25 USPATFULL

DETD . . . enhancers of this invention. Scalp conditions such as alopecia arcata may be treated more effectively by applying agents such as **minoxidil** in **combination** with one of the enhancers of this invention directly to the scalp.

DETD Transdermal patches containing **progesterone** with the following composition are prepared.

DETD 9.2 g of PDMS-382 (Dow Corning) pre-polymer, 300 mg of **progesterone** and 500 mg of 5-Amino-5-ethyl-2-(3-heptyl)-1,3-dioxane are mixed. One drop of polymerization initiator is added and the

contents are thoroughly mixed. . . .

CLM What is claimed is:

. . . selected from the group consisting of estradiol, ethinyl estradiol and 1,25-dihydroxy-7-dehydrocholesterol; an antifertility agent selected

from the group consisting of **progesterone** and medroxyprogesterone; an antiasthmatic agent selected from the group consisting of theophylline, albuterol and metaproterenol; an antineoplastic and antiviral agent. . . .

. . . selected from the group consisting of estradiol, ethinyl estradiol and 1,25-dihydroxy-7-dehydrocholesterol; an antifertility agent selected

from the group consisting of **progesterone** and medroxyprogesterone; an antiasthmatic agent selected from the group consisting of theophylline, albuterol and metaproterenol; an antineoplastic and antiviral agent. . . .

AN 96:3758 USPATFULL

PI US 5482965 19960109

xidil .

The active agents can be administered in a single topical dosage formulation, or each active agent can be administered in. . . dosage formulation, e.g., in separate topical dosage formulations, or an oral dosage formulation of a compound of formula I in **combination** with a topical dosage formulation of, e.g., **minoxidil**, or a single oral dosage formulation of a compound of formula I and another 5.alpha.-reductase inhibitor, in **combination** with a topical dosage formulation of, e.g., **minoxidil**. See, e.g., U.S. Pat. Nos. 4,596,812, 4,139,619 and WO 92/02225, published Feb. 20, 1992, for dosages and formulations of calcium. . .

AN 2000:44109 USPATFULL  
PI US 6048869 20000411

L12 . . . 13 88' 1 3 540\* 42

Statistically slgn1f1cant t-, 4  
WO 94/17663 PCT/US94/01373

The data in the above table demonstrates the synergistic effects of the  
**block**:ing **testosterone** induced reIrmth. of the  
involuted rat ventral  
prostate.

O  
H2N N NH2  
" ri

N  
N

chemically **minoxidil** is designated as 2,4-pyrimidineadiamine,  
6-(1-  
piperidinyl)-,3-oxide. **Minoxidil** is the active ingredient in  
Rogaine®

which is sold as topical solution for stimulating hair growth by the  
Upjohn Company, Kalamazoo, Michigan. When **minoxidil** is utilized  
in

**combination** with 5-oc-reductase inhibitors, as described  
herein,

**minoxidil**

is preferably administered analogously to its commercial form.

AN  
1994017663  
P

DETD Another approach described in United States Patent No. 5,183,817 is to utilize retinoids or mixtures thereof in **combination** with **minoxidil** and/or **minoxidil**-type compounds in stimulating or increasing the rate at which hair grows on mammalian skin. Such treatment does not reduce hormone production. It may. . .

disadvantages associated with this method are itching upon topical application, poor absorption, inconvenience in application, and the necessity of mussing of the hair. Furthermore, **progesterone** and **progesterone**-like compounds are cited as preferred inhibitors in United States Patent No. 5,053,403. However, because **progesterone** and **progesterone**-like compounds do not completely inhibit the conversion of testosterone to dihydrotestosterone, such agents do not provide suitable hair growth.

treatment of male-pattern baldness is finasteride, a synthetic 4-azasteroid compound, sold under the name Proscar<sup>1</sup>. Finasteride is structurally similar to **progesterone**. Proscar<sup>0</sup> has been used to shrink enlarged prostates by blocking the formation of DHT. However, Proscar<sup>0</sup> does not provide an efficacious treatment of. . .

LHRH antagonists, however, suppress **testosterone** formation by **blocking** LH release by competitive antagonism of LHRH binding at the pituitary receptor level. Accordingly, levels of dihydrotestosterone, the hormone principally responsible for causing male. . .

A

4/9, K/22 (Item 1 from file: 156)  
DIALOG(R) File 156:Toxline(R)  
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Language: ENGLISH

Document Type: JOURNAL ARTICLE

Journal Announcement: 9204

A 5 alpha-reductase inhibitor, finasteride, was administered orally at 0.5 mg/day, alone or in combination with topical 2% minoxidil, for 20 weeks to determine the effects on scalp hair growth in balding adult male stumptail macaque monkeys. A 7-day dose-finding study showed that both 0.5- and 2.0-mg doses of the drug produced a similar diminution in serum dihydrotestosterone (DHT) in male stumptails. Hair growth was evaluated by shaving and weighing scalp hair at baseline and at 4-week intervals during treatment to obtain cumulative delta hair weight (sum of the 4-week changes in hair weight from baseline) for the 20-week study. The activity of the 5 alpha-reductase enzyme was assessed by RIA of serum testosterone (T) and DHT at 4-week intervals. The combination of finasteride and minoxidil generated significant augmentation of hair weight (additive effect) compared to either drug alone. Finasteride increased hair weight in four of five monkeys. When the data of the one nonresponsive monkey were excluded, finasteride elicited a significant elevation in hair weight compared to topical vehicle alone. Minoxidil also evoked a significant increase in hair weight compared to vehicle alone. Serum T was unchanged, whereas serum DHT was significantly depressed in monkeys that received either finasteride or the combination of finasteride and minoxidil. These data suggest that inhibition of the conversion of T to DHT by this 5 alpha-reductase inhibitor reverses the balding process and enhances hair regrowth by topical minoxidil in the male balding stumptail macaque.

Tags: Animal; Male

Descriptors/Keywords: Androstenes--Pharmacology--PD; \*Azasteroids--Pharmacology--PD; \*Hair--Drug Effects--DE; \*Minoxidil--Pharmacology--PD; \*Testosterone 5-alpha-Reductase--Antagonists and Inhibitors--AI; Administration, Oral; Administration, Topical; Androstenes--Administration and Dosage--AD; Azasteroids--Administration and Dosage--AD; Chromatography, High Pressure Liquid; Drug Interactions; Hair--Physiology--PH; Macaca; Minoxidil--Administration and Dosage--AD; Minoxidil--Urine--UR; Reference Values; Stanolone--Blood--BL; Testosterone--Blood--BL

CAS Registry No.: 0 (Androstenes); 0 (Azasteroids); 38304-91-5 (Minoxidil); 521-18-6 (Stanolone); 57-85-2 (Testosterone); 98319-26-7 (Finasteride)

Enzyme No.: EC 1.3.99.5 (Testosterone 5-alpha-Reductase)

Hair growth effects of oral administration of finasteride, a steroid 5 alpha-reductase inhibitor, alone and...

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8/3, K/16 (Item 1 from file: 453)  
DIALOG(R) File 453:Drugs of the Future  
(c) 2001 Prous Science. All rts. reserv.

00145770 (Structure Image Available)  
ENTRY NUMBER: 145770  
DRUG NAME: MK-906  
YM-152  
GENERIC NAME: Finasteride (recommended INN; BAN; USAN)  
BRAND NAME: Andozac  
Chibro-Proscar (Merck Sharp & Dohme, FR)  
Finastid  
Prodel (Yamanouchi, JP)  
Propecia (Merck & Co., US;Merck Sharp & Dohme, ES, FR, IT)  
Proscar (Banyu, JP;Merck Sharp & Dohme, ES, GB, IT, SE, US)  
Prostide (Sigma-Tau, IT)  
CHEM NAME: 17beta-(N-tert-Butylcarbamoyl)-4-aza-5alpha-androst-1-en-3-one  
N-tert-Butyl-3-oxo-4-aza-5alpha-androst-1-ene-17beta-carboxamide  
FORMULA: C23H36N2O2  
CAS REG. NO.: 98319-26-7  
DEVEL. PHASE: Launched (201992)  
ORIGINATOR: Banyu  
DuPont Pharmaceuticals  
Merck & Co.  
Merck Sharp & Dohme  
LICENSEE: Sigma-Tau  
Yamanouchi  
CLASS: 35560 (Benign Prostatic Hyperplasia Therapy)  
41515 (Hirsutism Therapy)  
59813 (Hair Growth Stimulants)  
40120 (Antiandrogens)  
78335 (Steroid 5alpha-Reductase Inhibitors)  
SYNTHESIS: 20604  
68332  
65430  
CONTEXT TABLE: 35560C (Benign Prostatic Hyperplasia Therapy)

...p.o. finasteride was found to reverse balding and enhance hair regrowth alone and in **combination** with topical **minoxidil** via inhibition of conversion of **testosterone** to dihydrotestosterone.  
(60)

In healthy volunteers administered oral (14C)-finasteride (38.1 mg), mean peak...

8/3, K/14 (Item 1 from file: 377)  
DIALOG(R) File 377:Derwent Drug File  
(c) 2001 Derwent Info Ltd. All rts. reserv.

00538206 DERWENT ACCESSION NUMBER: 93-27559  
Isotretinoin Reduces Amount of **Dihydrotestosterone** Produced in Scalp Skin and Promotes Hair Growth in **Combination With Minoxidil**.  
Bazzano G S; Terezakis N K  
J.Invest.Dermatol. 100, No. 4, 545, 1993

Isotretinoin Reduces Amount of **Dihydrotestosterone** Produced in Scalp Skin and Promotes Hair Growth in **Combination With Minoxidil**.

ABSTRACT:

...could reduce the size of scalp sebaceous glands and thereby reduce their capacity to produce **dihydrotestosterone** (DHT, androstanolone), 8 patients were evaluated following isotretinoin treatment. Scalp sebum secretion was reduced and tritiated **testosterone** conversion to DHT in whole scalp biopsies was reduced. In another group of 10 patients isotretinoin in **combination** with **minoxidil** promoted hair growth. The results suggest that topical 13-cis retinoic acid (isotretinoin) can suppress DHT production and in **combination** with **minoxidil**, stimulates hair growth in a synergistic manner. (congress

16/3, K/11 (Item 5 from file: 34)  
DIALOG(R) File 34:SciSearch(R) Cited Ref Sci  
(c) 2001 Inst for Sci Info. All rts. reserv.

03081929 Genuine Article#: NC132 No. References: 31  
Title: ENDOCRINE PROPERTIES OF THE TESTOSTERONE 5-ALPHA-REDUCTASE INHIBITOR  
TUROSTERIDE (FCE-26073)  
Author(s): DISALLE E; BRIATICO G; GIUDICI D; ORNATI G; PANZERI A  
Corporate Source: FARMITALIA CARLO ERBA SPA, R&D, ENDOCRINOL LAB, VIA GIOVANNI  
XXIII/I-20014 NERVIANO//ITALY/  
Journal: JOURNAL OF STEROID BIOCHEMISTRY AND MOLECULAR BIOLOGY, 1994, V48,  
N2-3 (FEB), P241-248  
ISSN: 0960-0760  
Language: ENGLISH Document Type: ARTICLE (Abstract Available)

...Abstract: androgens (relative binding affinity, RBA, 0.004%), estrogens  
(less-than-or-equal-to 0.005%), **progesterone** (<0.005%),  
glucocorticoids (<0.01%) and mineralocorticoids (<0.03%). Its  
biochemical profile was similar to that of **finasteride**, whereas  
4-MA (17beta-N,N-diethyl-carbamoyl-4-methyl-4-aza-5alpha-androstan-3...  
...Identifiers--HUMAN STEROID 5-ALPHA-REDUCTASE; BENIGN PROSTATIC  
HYPERPLASIA; RAT; **FINASTERIDE**; DEHYDROGENASE; AROMATASE;  
ISOMERASE

16/3, K/10 (Item 4 from file: 34)  
DIALOG(R)File 34:SciSearch(R) Cited Ref Sci  
(c) 2001 Inst for Sci Info. All rts. reserv.

04683633 Genuine Article#: UA127 No. References: 35  
Title: EFFECT OF PROGESTERONE, TESTOSTERONE AND THEIR 5-ALPHA-REDUCED  
METABOLITES ON GFAP GENE-EXPRESSION IN TYPE-1 ASTROCYTES  
Author(s): MELCANGI RC; RIVA MA; FUMAGALLI F; MAGNAGHI V; RACAGNI G;  
MARTINI L  
Corporate Source: UNIV MILAN,INST PHARMACOL SCI,DEPT ENDOCRINOL,VIA G  
BALZARETTI 9/I-20133 MILAN//ITALY/; UNIV MILAN,INST PHARMACOL SCI,CTR  
NEUROPHARMACOL/I-20133 MILAN//ITALY/; HOSP SAN RAFFAELE,DIBIT/I-20132  
MILAN//ITALY/  
Journal: BRAIN RESEARCH, 1996, V711, N1-2 (MAR 4), P10-15  
ISSN: 0006-8993  
Language: ENGLISH Document Type: ARTICLE (Abstract Available)

Title: EFFECT OF PROGESTERONE, TESTOSTERONE AND THEIR 5-ALPHA-REDUCED  
METABOLITES ON GFAP GENE-EXPRESSION IN TYPE-1 ASTROCYTES  
...Abstract: typical of steroid target cells, such as 5 alpha-reductase,  
which converts testosterone (T) and **progesterone** (P) into their  
respective 5 alpha-reduced metabolites, and the 3 alpha-hydroxysteroid  
dehydrogenase (3...  
...its conversion into DHP; this hypothesis has been confirmed by showing  
that the addition of **finasteride** (a specific blocker of the 5  
alpha-reductase) is able to completely abolish the effect...

16/3, K/7 (Item 1 from file: 34)  
DIALOG(R) File 34:SciSearch(R) Cited Ref Sci  
(c) 2001 Inst for Sci Info. All rts. reserv.

07329820 Genuine Article#: 151GB No. References: 43  
Title: An ongoing validation of a Tier I screening battery for detecting  
endocrine-active compounds (EACs)  
Author(s): OConnor JC; Cook JC (REPRINT) ; Slone TW; Makovec GT; Frame SR;  
Davis LG  
Corporate Source: DUPONT CO INC, HASKELL LAB TOXICOL & IND MED, POB  
50/NEWARK//DE/19714 (REPRINT); DUPONT CO INC, HASKELL LAB TOXICOL & IND  
MED/NEWARK//DE/19714  
Journal: TOXICOLOGICAL SCIENCES, 1998, V46, N1 (NOV), P45-60  
ISSN: 1096-6080 Publication date: 19981100  
Publisher: ACADEMIC PRESS INC JNL-COMP SUBSCRIPTIONS, 525 B ST, STE 1900,  
SAN DIEGO, CA 92101-4495  
Language: English Document Type: ARTICLE (ABSTRACT AVAILABLE)

...Abstract: receptor antagonist (flutamide, FLUT), a testosterone  
biosynthesis inhibitor (ketoconazole, KETO), a 5 alpha-reductase  
inhibitor (**finasteride**, FIN), and an aromatase inhibitor  
(anastrozole, ANA). The Tier I battery incorporates two short-term...  
...compounds that have the potential to act as agonists or antagonists to  
the estrogen, androgen, **progesterone**, or dopamine receptors,  
steroid biosynthesis inhibitors (aromatase, 5 alpha-reductase, and  
testosterone biosynthesis), or compounds that alter thyroid function.  
ICI administration decreased uterine estrogen and **progesterone**  
receptor number in the female battery, increased serum  
follicle-stimulating hormone (FSH) levels and caused...  
...Identifiers--TESTICULAR TOXICITY; ANDROGEN RECEPTOR; BORIC-ACID; RAT;  
TRANSCRIPTION; **5-ALPHA-REDUCTASE**; KETOCONAZOLE; ANTIANDROGEN;  
DERIVATIVES; **FINASTERIDE**

16/3, K/8 (Item 2 from file: 34)  
DIALOG(R) File 34:SciSearch(R) Cited Ref Sci  
(c) 2001 Inst for Sci Info. All rts. reserv.

05435885 Genuine Article#: VY583 No. References: 51  
Title: SCREENING FOR DRUG-INDUCED ALTERATIONS IN THE PRODUCTION AND RELEASE  
OF STEROID-HORMONES BY PORCINE ADRENOCORTICAL-CELLS IN-VITRO  
Author(s): JAGER LP; DEGRAAF GJ; WIDJAJAGREEFKES HCA  
Corporate Source: DLO, CENT VET INST, DEPT BIOCHEM & TOXICOL, POSTBUS  
65/NL-8200 AB LELYSTAD//NETHERLANDS/  
Journal: TOXICOLOGY IN VITRO, 1996, V10, N5 (OCT), P595-608  
ISSN: 0887-2333  
Language: ENGLISH Document Type: ARTICLE (Abstract Available)

...Abstract: potential to alter steroidogenesis, an in vitro model using  
porcine adrenocortical cells was developed. Pregnenolone,  
**progesterone**, deoxycorticosterone or corticosterone (all at 1 mu  
M) were used as substrates. Drug-induced changes...  
...pregnenolone, drug-induced effects on the release of nine steroids  
(aldosterone, corticosterone, cortisol, deoxycortisol, testosterone,  
**progesterone**, **HO-progesterone**, androstenedione,  
dehydroepiandrosterone) were monitored simultaneously. For assessment

of cell viability and the amount of steroids...  
...Aminoglutethimide inhibited the release of aldosterone with corticosterone as substrate, but not with deoxycorticosterone or **progesterone** as substrate, revealing an alternative pathway in the biogenesis of aldosterone by-passing corticosterone. Trilostane (0.1-1  $\mu$  M) completely blocked conversion of pregnenolone to **progesterone** and **OH-progesterone**; the release of androstanedione was at most only halved, whereas the release of dehydroepiandrosterone and...  
...enzymes involved in transformations at C21 and at C17, respectively. Cyproheptadine blocks all transformations with **progesterone** or **HO-progesterone** as starting point. **Finasteride** reduced the release of most steroids, except the androgens, presumably by inhibition of transformations at...  
...Identifiers--ALDOSTERONE BIOSYNTHESIS; ADRENAL STEROIDOGENESIS; IMIDAZOLE DERIVATIVES; DOSE KETOCONAZOLE; WEANED PIGS; IN-VITRO; ETOMIDATE; INHIBITION; CORTISOL; **5-ALPHA-REDUCTASE**